K012397

SEP 2 6 2001

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46250
(317) 576 - 3544

Contact Person: Kay A. Taylor

Date Prepared: July 25, 2001

Device Name

Proprietary name: Urisys 2400 Urine Test Strip

Common name: Reagent Strip for Urinalysis

Classification name: Urinary glucose, ketones, nitrite, protein, blood, bilirubin, urobilinogen, leukocytes (non-quantitative) and pH Test Systems

Device Description

The Urisys 2400 Urine Test Strips are used in conjunction with the Urisys 2400 photometer. The Urisys 2400 photometer is an automated urinalysis system, class I exempt device, regulation number 21CFR 862.2900. The Urisys 2400 photometer determines specific gravity, sample color, and sample clarity and reflectance measurements of test parameters on the Urisys 2400 Urine Test Strips.

510(k) Summary, Continued

Intended use

For semi-quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketone bodies, urobilinogen, bilirubin and blood in urine by reflectance photometry with the Urisys 2400 photometer.

Indications for Use

For semi-quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketone bodies, urobilinogen, bilirubin and blood in urine by reflectance photometry with the Urisys 2400 photometer.

Substantial Equivalence

The Urisys 2400 Urine Test Strip is substantially equivalent to other devices legally marketed in the United States. We claim equivalence to the Roche Diagnostics Chemstrip 10 S-UA test strips (K934042). Both products are designed to provide semi-quantitative urinalysis results using chemistry reagent strips that include pH, leukocytes, nitrite, protein, glucose, ketone, urobilinogen, bilirubin and blood reagent pad areas.

Substantial equivalence - similarities

The following table compares the Urisys 2400 Urine Test Strip with the predicate device.

Feature	Urisys 2400 Urine Test Strip	Chemstrip 10 S-UA
Intended Use	For semi-quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketone bodies, urobilinogen, bilirubin and blood in urine by reflectance photometry with the Urisys 2400 photometer.	For the semi-quantitative determination of Specific Gravity, pH, Leukocytes, Nitrite, Protein, Glucose, Ketones, Urobilinogen, Bilirubin and Blood in urine. Intended for use visually or on the Chemstrip Super UA Automated Urine Analyzer.
Architecture	Reagent test paper, mesh and absorbent paper laminated on plastic strip.	Reagent test paper, mesh and absorbent paper laminated on plastic strip.
Calibration method	Same	Calibration strips with specific reflectance values for calibration.
Storage	Store at 2°C-30°C.	At temperatures below 30°C, do not freeze.

Substantial equivalence – similarities, continued

Feature	Urisys 2400 Urine Test Strip	Chemstrip 10 S-UA
Intrinsic color compensation	Same	blank compensation pad correction
Measurement mode	Same, as well as urine color through reflectance readings of the compensation pad	photometric reflectance for pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes

Substantial equivalence – differences

The following table compares the Urisys 2400 Urine Test Strips with the predicate device.

Feature	Urisys 2400 Urine Test Strips	Chemstrip 10 S-UA
On-instrument storage	14 days	up to 10 hours
Urine application	Sample dispensed onto test strip	Test strip dipped into sample

Substantial equivalence – performance characteristics

The performance characteristics of the Urisys 2400 Urine Test Strips and the predicate device are provided in section IV.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Kay A. Taylor
Regulatory Affairs, Laboratory Systems
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

SEP 2 6 2001

Re: k012397
Trade/Device Name: Urisys 2400 Urinalysis Test System
Regulation Number: 21 CFR 862.1340
Regulation Name: Urinary glucose (non-quantitative) test system
Regulatory Class: Class II
Product Code: JIL
Regulation Number: 21 CFR 864.6550
Regulation Name: Occult blood test
Regulatory Class: Class II
Product Code: JIO
Dated: July 25, 2001
Received: July 27, 2001

Dear Ms. Taylor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): ~~N/A~~ K012397

Device Name: Urisys 2400 Urinalysis Test System

Indications For Use:

For semi-quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketone bodies, urobilinogen, bilirubin and blood in urine by reflectance photometry with the Urisys 2400 photometer.

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Kesia Alexander for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012397